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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,529	05/06/2002	Christopher Elkins	5470-269	4127

20792 7590 12/14/2005

MYERS BIGEL SIBLEY & SAJOVEC  
PO BOX 37428  
RALEIGH, NC 27627

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/030,529	<b>Applicant(s)</b> ELKINS, CHRISTOPHER	
	<b>Examiner</b> S. Devi, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 8, 9, 14-18 and 23-25 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 ~~is/are~~ allowed.
- 6) ☒ Claim(s) 1, 5, 8, 9, 14-18 and 23-25 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **RESPONSE TO APPLICANT'S AMENDMENT**

### **Applicant's Amendment**

- 1) Acknowledgment is made of Applicant's amendment filed 11/02/05 in response to the non-final Office Action mailed 08/02/05. With this, Applicant has amended the specification.

### **Status of Claims**

- 2) Claims 2, 4, 6, 7, 10-13, 19-22 and 26-28 have been canceled via the amendment filed 11/02/05.

Claims 1, 3, 5, 8, 9, 14-18 and 23-25 have been amended via the amendment filed 11/02/05.

Claims 1, 3, 5, 8, 9, 14-18 and 23-25 are pending and are under examination.

### **Prior Citation of Title 35 Sections**

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Moot**

- 5) The objection to claim 2 made in paragraph 15 of the Office Action mailed 08/02/05 is moot in light of Applicant's cancellation of the claim.

### **Objection(s) Withdrawn**

- 6) The objection to the specification made in paragraph 7(A) of the Office Action mailed 08/02/05 is withdrawn in light of Applicant's amendment to the specification.

- 7) The objection to the specification made in paragraph 7(C) of the Office Action mailed 08/02/05 is withdrawn in light of Applicant's amendment to the specification.

### **Objection(s) Maintained**

- 8) The objection to claim 5 made in paragraph 15 of the Office Action mailed 08/02/05 is maintained for reasons set forth therein.

**9)** The objection to the specification made in paragraph 7(B) of the Office Action mailed 08/02/05 is maintained for reasons set forth therein and herebelow.

The instant specification continues to include trademark recitations that are not capitalized. For example, see 'Adjuvax', 'Titermax', and 'carbopol' in the paragraph bridging pages 30 and 31; 'carbopol' in the first full paragraph of page 34; 'Centrilutor' in paragraph bridging pages 38 and 39 of the specification.

### **Rejection(s) Moot**

**10)** The rejection of claim 10 made in paragraph 9 of the Office Action mailed 08/02/05 under 35 U.S.C § 101 as being directed to non-statutory subject matter, is moot in light of Applicant's cancellation of the claim.

**11)** The rejection of claim 28 made in paragraph 9 of the Office Action mailed 08/02/05 under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of Applicant's cancellation of the claim.

**12)** The rejection of claims 2 and 10 made in paragraph 12(a) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claims.

**13)** The rejection of claim 2 made in paragraph 12(c) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claim.

**14)** The rejection of claim 10 made in paragraph 12(e) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claim.

**15)** The rejection of claim 10 made in paragraph 12(h) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claim.

**16)** The rejection of claim 28 made in paragraph 12(r) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claim.

**17)** The rejection of claim 28 made in paragraph 12(s) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claim.

**18)** The rejection of claims 2, 10 and 28 made in paragraph 12(t) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicant's cancellation of the claims.

**19)** The rejection of claims 2 and 10 made in paragraph 14 of the Office Action mailed 08/02/05 under 35 U.S.C § 102(b) as being anticipated by Skurnik *et al.* (*Mol. Microbiol.* 3: 517-529, 1989 – Applicants' IDS), is moot in light of Applicant's cancellation of the claims.

### **Rejection(s) Withdrawn**

**20)** The rejection of claims 14 and 15 made in paragraph 9 of the Office Action mailed 08/02/05 under 35 U.S.C § 101 as being directed to non-statutory subject matter, is withdrawn in light of Applicant's amendment to the claims.

**21)** The rejection of claims 23-25 made in paragraph 10 of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicant's amendments to the claims.

**22)** The rejection of claims 1, 3, 5, 17 and 18 made in paragraph 12(a) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

**23)** The rejection of claim 1 made in paragraph 12(b) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**24)** The rejection of claim 5 made in paragraph 12(c) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**25)** The rejection of claims 8, 14 and 23 made in paragraph 12(d) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

**26)** The rejection of claims 3 and 5 made in paragraph 12(e) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

**27)** The rejection of claim 9 made in paragraph 12(e) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**28)** The rejection of claim 25 made in paragraph 12(g) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**29)** The rejection of claims 15 and 16 made in paragraph 12(i) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claims.

**30)** The rejection of claim 18 made in paragraph 12(l) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**31)** The rejection of claim 18 made in paragraph 12(m) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**32)** The rejection of claim 18 made in paragraph 12(n) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**33)** The rejection of claim 18 made in paragraph 12(o) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**34)** The rejection of claim 24 made in paragraph 12(p) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**35)** The rejection of claim 24 made in paragraph 12(q) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of

Applicant's amendment to the claim.

**36)** The rejection of claims 3, 5, 8, 9, 14-18 and 23-25 made in paragraph 12(t) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.

**37)** The rejection of claim 15 made in paragraph 12(k) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.

**38)** The rejection of claims 1, 8 and 9 made in paragraph 14 of the Office Action mailed 08/02/05 under 35 U.S.C § 102(b) as being anticipated by Skurnik *et al.* (*Mol. Microbiol.* 3: 517-529, 1989 – Applicants' IDS), is withdrawn in light of Applicant's amendment to the base claim.

### **Rejection(s) Maintained**

**39)** The rejection of claim 9 made in paragraph 9 of the Office Action mailed 08/02/05 under 35 U.S.C § 101 as being directed to non-statutory subject matter, is maintained for reasons set forth therein.

**40)** The rejection of claim 17 made in paragraph 12(j) of the Office Action mailed 08/02/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicant contends that support for the term 'fragment' as it is used in claim 17 is at lines 4-7 of page 11 of the specification. Applicant submits that 'fragments' are stated herein as those nucleic acid sequences which are greater than 60 nucleotides in length, and most preferably includes fragments that are at least 100 nucleotides or at least 1000 nucleotides, and at least 10,000 nucleotides in length. With this, Applicant concludes that the term 'fragment' as used in claim 17 is therefore definite and clear.

Applicant's arguments have been carefully considered, but are not persuasive. Claim 17 includes two recitations of 'a fragment', i.e., a fragment of the protein recited in lines 1-4; and a fragment of the polynucleotide recited in line 6 of the claim. The 'fragment' described at lines 4-7 of page 11 of the specification is unrelated to the 'polypeptide fragment'. Instead, this part of the specification provides an open or non-limiting description of a 'fragment' of a polynucleotide. The scope of the term 'fragment' is unclear. The rejection stands.

To obviate the rejection, it is suggested that Applicant replace the limitation 'a fragment of a polynucleotide sequence' in line 6 of the claim with --a fragment of a polynucleotide sequence greater than 60 nucleotides in length--. It is further suggested that Applicant replace the limitation 'a fragment' in line 4 of the claim with the limitation --an antigenic determinant-- since such a limitation is supported in the first full paragraph of page 9 of the specification.

**41)** The rejection of claims 14-16 made in paragraph 14 of the Office Action mailed 08/02/05 under 35 U.S.C § 102(b) as being anticipated by Skurnik *et al.* (*Mol. Microbiol.* 3: 517-529, 1989 – Applicants' IDS), is maintained for reasons set forth therein and herebelow.

Skurnik's isolated gene or polynucleotide comprising several stretches of 12-15 contiguous nucleotide sequences, GGTGTAGGCAAA, GTAGGAGGTTATAGA, GCATTAGCCATTGGT, and AAAGCGGGTGTAGCG encoding the DsrA, GlyValGlyLys, ValGlyGlyTyrArg, AlaLeuAlaIleGly, and LysAlaGlyValAlaTyr, as well as the single-stranded probe thereof, recombinant plasmids comprising the same, and *E. coli* cell transformed with the plasmid, still anticipate the products claimed in claims 14-16. Skurnik's isolated gene or polynucleotide is expected to comprise an antisense oligonucleotide therein of sufficient length that is at least partly complementary to the polynucleotide of claim 1 and hybridizes thereto under 'physiologic conditions'. The specification describes that an antisense oligonucleotide can be 8 nucleotides in length (see lines 3 and 4 on page 29 of the specification), and Skurnik's isolated gene or polynucleotide clearly comprises such an antisense oligonucleotide. The rejection stands.

### **New Rejection(s) Based on Applicant's Amendment**

The new rejections set forth below are necessitated by Applicant's amendments to the claims.

#### **Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)**

**42)** Claim 18 is rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 18, as amended, now includes the limitations: 'under conditions whereby a nucleic acid hybridization complex can form if a polynucleotide which encodes DsrA is present in the



biological sample'. Applicant does not point to a specific part of the specification that provides descriptive support for the added limitations. A review of the specification indicates lack of descriptive support for these added limitations. Therefore, the above-identified limitations in the claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitations, or remove the new matter from the claim.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**43)** Claims 1, 5, 8, 9, 14-16, 18 and 23-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 1 is vague in the limitation 'as exemplified by' (see line 9), because it is unclear what conditions are excluded by this limitation. It is suggested that Applicant replace the limitation with --comprising--.

(b) Claim 1 is vague in the limitation 'as exemplified by' (see line 9), because it is unclear what conditions are excluded by this limitation. It is suggested that Applicant replace the limitation with --represented by--.

(c) Claim 1 is vague, indefinite and/or incorrect in the limitation: 'polynucleotides that hybridize .... which encode a ..... DsrA' [Emphasis added]. See parts (c) and (d) of the claim. For the purpose of distinctly claiming the subject matter, it is suggested that Applicant replace the limitation with --polynucleotide that hybridizes ..... which encodes a .... DsrA--.

(d) Claim 18 is vague, indefinite and/or lacks proper antecedent basis in the limitation 'DsrA in the biological sample' (see last line), because it is unclear whether or not this DsrA is different from the one recited in line 2 of the claim. It is suggested that Applicant provide proper antecedent basis by replacing the limitation with --the DsrA in the biological sample--.

(e) Claims 5, 8, 9, 14-16 and 23-25, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the vagueness and/or indefiniteness identified above in the base claim.

### Remarks

**44)** Claims 1, 5, 8, 9, 14-18 and 23-25 stand rejected. Claim 3 is allowed.

For clarity, it is suggested that Applicant replace the limitation 'a DNA' in line 2 of claim 5 with --the DNA--.

**45)** Applicant's amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**46)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The central Fax number for submission of amendments, responses and papers is (571) 273-8300.

**47)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**48)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The

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Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2005

  
S. DEVI, PH.D.  
PRIMARY EXAMINER